

In the Claims:

The following is a complete listing of the claims, intended to replace any claims previously set forth in this matter. Please amend the claims as shown.

Claims 1-200 are Previously CANCELLED.

Claims 201-249 are CANCELLED.

250. (New) A proprietary new use for, or characteristic of, a product of manufacture or device, wherein the identity of the new use or useful characteristic was derived according to the steps comprising:

- accessing one or more data sources, wherein at least one data source comprises adverse event data;

- analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device;

- identifying at least one new essential adverse event associated with the product or device from the adverse event data, and then responsive to identification, identifying the at least one new characteristic of, or use for, the product or device;

- documenting inventorship of the at least one new characteristic of, or use for, the product or device; and

- creating a proprietary essential adverse event information database which stores data regarding the at least one new characteristic or use, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication.

251. (New) The new use or characteristic of claim 250, the steps further comprising determining value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event.

252. (New) The new use or characteristic of claim 251, the steps further comprising commercializing the at least one new use or characteristic.

253. (New) The new use or characteristic of claim 252, the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information.
254. (New) The new use or characteristic of claim 252, wherein the product is commercially available.
255. (New) The new use or characteristic of claim 253, wherein commercializing further comprises formatting the data relating to at least one new adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product or device.
256. (New) The new use or characteristic of claim 250, wherein at least one data source comprises information relating to patents and patent applications.
257. (New) The new use or characteristic of claim 250, wherein at least one data source comprises information relating to raw commercial or sales data.
258. (New) The new use or characteristic of claim 252, wherein at least one adverse event comprises a drug interaction.
259. (New) The new use or characteristic of claim 258, wherein at least one data source comprises information relating to raw commercial or sales data.
260. (New) The new use or characteristic of claim 250, wherein the essential adverse event data is proprietary.
261. (New) The new use or characteristic of claim 250, wherein the product is medical.
262. (New) The new use or characteristic of claim 252, wherein the product is medical.
263. (New) The new use or characteristic of claim 262, wherein the medical product is a generic drug.
264. (New) The new use or characteristic of claim 250, wherein the product is non-medical.

265. (New) The new use or characteristic of claim 252, wherein the product is non-medical.
266. (New) The new use or characteristic of claim 250, wherein the device is medical.
267. (New) The new use or characteristic of claim 252, wherein the device is medical.
268. (New) The new use or characteristic of claim 250, wherein the device is non-medical.
269. (New) The new use or characteristic of claim 252, wherein the device is non-medical.
270. (New) A proprietary kit containing a product or device, and labeling notifying a user of at least one new essential adverse event for the product or device, wherein the kit is used in accordance with the proprietary new use or characteristic of claim 250.
271. (New) A proprietary kit containing a product or device, and labeling notifying a user of at least one new essential adverse event for the product or device, wherein the kit is created in accordance with the proprietary new use or characteristic of claim 259.
272. (New) The proprietary new use or characteristic of claim 250, further comprising identifying the new use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.
273. (New) The proprietary new use or characteristic of claim 253, further comprising identifying the new use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.
274. (New) The new use or characteristic of claim 250, wherein the at least one adverse event is a drug interaction.
275. (New) The new use or characteristic of claim 274, wherein the drug interaction pertains to efficacy of a drug.
276. (New) The new use or characteristic of claim 275, wherein the new use comprises a restricted use in at least one population subgroup when there is observed to

be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

277. (New) The new use or characteristic of claim 275, wherein at least one data source comprises information relating to raw commercial or sales data.

278. (New) The new use or characteristic of claim 277, wherein at least one new adverse event is other than a chronic immune mediated disorder.

279. (New) The new use or characteristic of claim 278, the steps further comprising determining value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event.

280. (New) The new use or characteristic of claim 279, the steps further comprising commercializing the at least one new use or characteristic, and wherein the product or device is commercially available.

281. (New) The new use or characteristic of claim 250, wherein at least one new essential adverse event comprises an drug interaction wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

282. (New) The new use or characteristic of claim 252, wherein at least one new essential adverse event comprises a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

283. (New) The proprietary new use or characteristic of claim 250, wherein the at least one adverse event data source comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

284. (New) The proprietary new use or characteristic of claim 250, wherein the at least one adverse event data source comprises information regarding amount of use of the product or device or duration of exposure to the product or device by subjects.

285. (New) The proprietary new use or characteristic of 250, wherein the at least one new use of the product or device is a restricted use in at least one population subgroup,

when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the new adverse event is one other than a chronic immune mediated disorder.

286. (New) The proprietary new use or characteristic of 252, wherein the at least one new use of the product or device is a restricted use in at least one population subgroup, when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the new adverse event is one other than a chronic immune mediated disorder.

287. (New) The proprietary new use or characteristic of claim 250, wherein the product or device is commercially available, the steps further comprising identifying the new use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

288. (New) The proprietary new use or characteristic of claim 251, wherein the product or device is commercially available, the steps further comprising identifying the new use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

289. (New) The proprietary new use or characteristic of claim 252, wherein the product or device is commercially available, the steps further comprising identifying the new use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

290. (New) The proprietary new use or characteristic of claim 259, wherein the product or device is commercially available, the steps further comprising identifying the new use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

291. (New) The proprietary new use or characteristic of claim 250, the steps further comprising documenting date of inventorship.

292. (New) The proprietary new use or characteristic of claim 250, wherein at least one adverse event data source comprises raw data from a plurality of different adverse events.

293. (New) The proprietary new use or characteristic of 250, wherein the product or device is commercially available, and the new use is further identified as comprising restricting exposure of the product or device to one of the high risk associated groups selected from the group consisting of: high or low temperatures, chemicals, surfaces, pressures, electricity and sparks; or contact of the product or device with one of the group selected from the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the consumer; or exposure to a subpopulation group selected from the group consisting of children, pregnant women, consumers with specific allergies or medical conditions and animals; or exposure to a subpopulation defined by at least one consumer-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, and use of medicines or medical devices.

294. (New) The proprietary new use or characteristic of 250 where at least one new essential adverse event database is computerized.